EDUCATION PLATFORM

Seminar Series:

Facts and pitfalls of observational studies - How to plan and conduct HRO projects

Q&A from the session

"Data sharing and open research data – details for HRO projects"

Nov 13, 2024

- Difference pseudonymisation vs. anonymisation and specific requirements
    - We were unfortunately not able to cover this topic in the data sharing session, it is too complex. We are thinking about doing a separate session on pseudonymisation vs. anonymisation, so stay tuned for more HRO lunches.
- How was the original unstructured data for this network (SPHN) "curated"? I.e. how could it be brought to be of sufficient quality to compare it with data from other centers?
    - SPHN developed a framework based on a strong semantic layer of information, and graph technologies for the exchange layer, which can be extended by the individual projects to fit their purposes. Thus, a universal exchange language for healthcare is established, using the "words" from various international standard vocabularies (such as SNOMED CT or LOINC), a simple "grammar" (subject-predicate-object; expressed in RDF), and additional SPHN guidelines and rules to establish good practices for FAIR data.
- Is it a problem for SPHN if a center changes its clinical information system, for example from KISIM to Epic?
    - Change in clinical information system would mean more effort to pull out the data
    - But even if everybody would use the same clinical information system, it would not solve the problems around the interoperability
- Does SPHN provide a tool to pseudonymise clinical data to be shared
    - At each hospital, the structured data from the primary clinical information systems flow into a Clinical Data Warehouse of the hospital (a big database that brings in most of the clinical data). Then, each hospital has the task to pseudonymise, clean, in general curate the data and definitely harmonize them to the common schema/ontologies that SPHN has defined. Then, there is another quality check in overall SPHN data harmonization pipeline with extra tools provided, and then sent from the hospital to BioMedIT. This is a birds eye view of how data is collected, curated, harmonized. A lot of details behind this.
    - SPHN does not provide a specific tool for pseudonymisation itself, but
        - it provides Guidelines and a hands on template to assess the risk of identification and that are documenting the selected de-identification rules. https://sphn.ch/network/data-coordination-center/de-identification/
        - it provides an open source tool, the SPHN Connector, that simplifies the onboarding process, allowing hospitals to join the SPHN ecosystem with limited efforts. https://sphn.ch/2023/10/19/sphn-connector-public-release/

- Is there only one Data Access Committee (DAC) for all data at the USB? Or do projects have their individual DACs?
    - Can also be project-specific, but the independence might become problematic
    - Depends on requirements of funders, journals etc. if DAC needs to be independent
- Who has to sign the Data Transfer and Use Agreement (DTUA) - only the Investigator?
    - The institution as legal entity has to approve the project and its legal agreement --> usually it is a duly authorized representative (Head of department, CMO or CEO) of the hospital and the local project leader (researcher)
    - Researcher is usually not allowed to sign alone
- Who manages withdrawal of patient consent (for reuse of their data)?
    - Depends on the hospital --> usually each hospital is obliged to update the status of the consent once a patient has withdrawn it. For the reuse of data, only data with a valid status of consent given is shared.
    - Please also refer to the previous HRO lunch session: Consent, with a great example from CHUV
- Did I understand correctly that you recommend to make metadata available without restrictions? What metadata are you referring to?
    - As long as it is not sensitive data or they are protected by any IP that has to be respected, it is highly beneficial
    - As for the metadata itself, the MF-DAC recommends to share at least the codebook. Additionally it is beneficial to also publish the study protocol.
- Who decides which data are shared? Or do you provide always minimal data sets?
    - Depends on different factors, e.g. which data are requested, which data are necessary to reproduce research results, which data have been collected, …
    - Generally the idea is only to share as much data as necessary for the request made
    - For routinely collected data, in most hospitals, the established Data Governance Boards are reviewing and approving the data sharing requests in multi-center projects.
- Sharing of data collected in the context of a national multicentric study with 3rd parties (not part of consortium): is the description of a Data Access Committee (DAC) part of the Consortium Agreement or of the Data Transfer and Use Agreement (DTUA)?
    - The Consortium of a multi-center research project requires a consortium agreement, which contains a certain governance structure. This includes an executive board that for example would approve data sharing requests by third parties. It can also be established as separate DAC in parallel to the executive board, depending on the project purpose. A registry, for example, would establish a DAC, since the registry is meant to share sensitive personal data with third parties very often.
- Who is producing the metadata, how are they paid?
    - Metadata is usually produced along the study (e.g. codebook) but it might be beneficial to collect and store the metadata already with the sharing in mind

    - Metadata are also descriptions of the disease studied, randomization process etc., NCT numbers

- Are pseudonymised data still personal data if you do not have access to the key?
    - As long as there IS a key, it does not matter if you have access to it, the data is still coded/pseudonymised personal data
- Validation criteria of real world data from different context, e.g. health insurance data vs data from patient records vs prospective observational studies or registries
    - Using data that was collected for different purposes under different legal regulations and different governance is generally possible but needs a careful validation of consent status and de-identification type. Combination might be, however, very limited due to limited interoperability status (different or no harmonised semantic standards/terminologies).
- To what extent is it possible to share medical data in open research data? Do guidelines exist?
    - Please refer to the video and the slides.
    - Summary/short answer: Open research data generally exist, but need to be differentiated in terms of their sensitivity and related governance. Personal data is usually only available under strict governance processes and upon approval of the institution and completed legal agreement, whereas aggregated result data can be shared without restrictions. In general, FAIR data cannot be open data.
- When publishing, journals ask researchers to share their data sets. When / what data sets can be made available, and under which conditions?
    - Please refer to the video and the slides.
    - Summary/short answer: Non-sensitive information can be made accessible in an open access way. Sensitive information is best handed over to a dedicated Data Access Committee that takes care of any third party requests.
- When is a Data Transfer and Use Agreement (DTUA) and when is a Data Transfer and Processing Agreement (DTPA) necessary?
    - DTUA (Data Transfer and Use Agreement): Whenever personal data (and in some cases also for anonymised data) is shared (transferred and used) with another party/institution; the conditions under which data is disclosed need to be regulated in compliance with Swiss legislation.
    - DTPA (Data Transfer and Processing Agreement): Transfer of data to an external processor to host and analyse within the scope of the project. The processor has no interest in the results. For example if the project is using the secure BioMedIT network (e.g. sciCORE).
- When is a data transfer agreement mandatory?
    - See above. Usually a transfer of data goes along with usage of data, for which a Data Transfer and Use Agreement (DTUA) needs to be completed. The “U” is exclusively reflecting the conditions under which data is used for the project and what security measures apply for transfer and use.

- Set up (templates) for contracts

    - See SPHN Legal Agreements templates: https://sphn.ch/services/dtua/

- For the ethics submission, we were not sure when and for whom to set up a contract when we worked on a HRO project lately (where many collaborators from different hospitals and universities were involved)
    - When collaborating with multiple partners, usually a consortium agreement with an including Data Transfer and Use Agreement (DTUA) is supposed to be completed. This regulates the principles of collaboration such as the governance and data disclosure conditions. All parties that are involved in the project that are providing or using data are included. The legal department and CTUs or SPHN provide support to complete the agreements. Approved are such agreements usually by the head of the research department and the project leader (PL).
- What criteria need to be met for a contract to be binding, and what signatures is required depending on the origin of the data, samples and storage location?
    - If the contract is signed by the project leader (PL) and a duly authorized person of the involved institutions the contract is binding until it is terminated (conditions are set in the agreement). Signatures might depend on the organisation of the institution and on the origin of data/sample. The legal department/Data Governance Board decides.
- If we share data with a global data registry, does the ethics approval for further use need to be sought in Switzerland every time that data from this registry (including Swiss data) is analysed (anywhere in the world), or only if the data is analysed in Switzerland? (We already have the approval for the generic protocol, but not for future analyses).
    - An ethics approval is needed every time you analyse a new research question in a center in Switzerland. Sometimes the initial approval includes an approval for "Nested Projects"
    - If the research question is answered in another country, the coordinating bodies of this country would contact swissethics
- Differences in legal requirements with regards to data sharing in Switzerland versus other European countries? Are the legal requirements for data sharing harmonised across the EU countries?
    - There are big differences, and not a lot of harmonisation – if you have specific questions, please contact your local CTU. This is also due to the fact that Switzerland has a slightly different legislation. But in general the way how routinely collected data, for example, are shared are not that different (Consent basis is similar)
- We are running a registry and often have to deal with contracts for sharing data for international registries. We are interested in all information in this regard.
    - The SPHN legal agreements can be completed for exchange with international partners. Most importantly international partners need to comply with the same security requirements.
- I am interested in the topic of open research data for secondary usage, i.e. specifically machine learning or AI related activities. I do not have a specific question, however this is my interest. I am principal investigator of a number of AI related research project involving safety critical systems and health is often a use case.

    - Open research data sharing is not specific to AI or not, please refer to the presentation slides and video.
    - For the legal aspects, please contact your local CTU (too complex to answer in this format)

- How to share patient data for open research and at the same time keep adequate privacy of this data?
    - Please refer to the video and the slides.
    - Summary/short answer: Measures have to be taken during data collection, when making data accessible, and when re-using data. Recommendation is to install an independent Data Access Committee that manages access to such data.
- I would like to learn more about the setup of the Data Sharing Agreement in the case of HRO Chapter 2 and HRO Chapter 3 projects in Switzerland. Is it mandatory or not?
    - Yes, such agreements or contracts are always mandatory when personal data is shared with other parties. Please refer to the video and the slides for more information.
- If I have General Consent (GC) and leaflet and a registry project is company sponsored, should the company sign a Data Sharing Agreement with the hospitals?
    - If the data is collected initially by the hospitals via the GC, then the company needs to sign an agreement. The hospital is obliged to make sure adequate security measures to protect patient privacy are implemented in the project
- The legal representative signature on the General Consent (GC) is valid for example if the patient is on mechanical ventilation in the Intensive Care Unit (ICU)? (It would be nice to understand all scenarios: if the patient is awake and mentality capable to sign GC, if patient dies)?
    - The signature of the representative is valid as long as patient is not capable of consenting by himself
- Company sponsored registry: leaflet is a must or optional? In the case that is mandatory to provide it to the patient, who is responsible? Hospital or the company?
    - Depends in which form data is collected. If it is pseudonymised data then it is mandatory to provide information. In general, information is always recommended. If it is genetic data or samples then written consent is mandatory. Responsibility is always with the sponsor to ensure that the consent is valid and rightfully collected.
- Biobanks: re-use of data: how specific does the upcoming question have to be related to the primary question we collected the material for (and have consent for)?
    - If it is the General Consent then the consent is given for projects that are not yet defined and the routinely collected sample can be used for such future projects.
    - In general, every new research question has to be approved by the ethics committee. The details depend on the individual case, please contact your local CTU to get more precise information.